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Kenneth F. Buechler

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EXAMINER

ALEXANDER, LYLE

ART UNIT

PAPER NUMBER

1743

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/613,650

Applicant(s)

BUECHLER, KENNETH F.

Examiner

Lyle A. Alexander

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74-84 and 92-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74-84 and 92-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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In response to Appellants' Appeal Brief, The Office has reconsidered the pending claims and grounds of rejection. The Office believes it is necessary to make new 35 USC 112 rejections and correct a typographical error in the 35 USC 102 statute applied for Stocker.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 74-84 and 92-100 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,458,852. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims "at least one zone" to bind an analyte and hydrophilic/hydrophobic regions to direct the fluid. The Office has read the claimed "grooves" having a depth of 0.1mm to 1.5mm on the claimed

"depression" between 1nm and 0.5 mm. The claimed reaction chamber and diagnostic element have been read on the claimed "plurality of discrete capture zones".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 74-81 and 92-100 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification does not teach the claimed "nonporous surface". Upon searching all of the parent application, USP 6,019,944 teaches "nonporous surface" in claims 5,6 and 12. This patent and the instant application have the same inventorship. If Applicant adds "nonporous" to the instant specification this rejection will be overcome.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 74-81 and 92-99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The structure of independent claims 74 and 92 are confusing. These claims state there is either a "nonporous smooth surface" or a "nonporous textured surface"

and capture zones on either of the above surfaces that can either be immobilized to the surface or immobilized on particles immobilized to the surface. The following permeation of the claimed subject matter is available for examination:

- I) a nonporous smooth surface with a receptor immobilized to the surface;
- II) a nonporous smooth surface with a receptor immobilized on particles immobilized to the surface;
- III) a nonporous textured surface with a receptor immobilized to the surface; and
- IV) a nonporous textured surface with a receptor immobilized on particles immobilized to the surface.

For the purposes of examination, the Office has interpreted the instant invention as the first scenario, of a nonporous smooth surface with a receptor immobilized to the surface. Claim 79 has been interpreted as the "one or more particles" being particles other than the alternative particles in the 1 nm to 5 micron range (e.g. there is no link of "particles" to the particles in claim 74). Clarification could be achieved by claiming --said particles--.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 74-81 and 92-99 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Stocker (USP 4,647,543).

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Stocker teaches a device for immunological testing of immobilized samples. Figure 6(a) a plate(2) comprising supports(1a) within a hydrophilic area(3) for sample capture and a surrounding hydrophobic area(4). This has been read on the claimed hydrophilic/capture zones and adjacent hydrophobic zones. Support(1a) has been read on the claimed particles that immobilize the sample. Column 6 lines 22-23 teach immobilizing the biological material on the surface. Also, column 7 lines 1-2 teach the sample is chemically bonded to the support. Column 5 lines 59+ and claim 8 teach the surface is not flat and has "depressions" where the sample can be trapped. Column 6 lines 55-58 teach the depth of the depressions is a "reliable finite distance greater than or equal to zero". This surface could be read on either the "nonporous smooth surface" or the "nonporous textured surface". For the purposes of examination, the Office will only consider the "nonporous smooth surface". Column 8 lines 5-7 teach use of monoclonal antibodies. Column 7 lines 33-45 teach glass particles adhered to the plate.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 82 and 100 rejected under 35 U.S.C. 103(a) as being unpatentable over Stocker alone or further in view of Anawls et al. or Rohr.

See Stocker supra.

Stocker is silent to the claimed material of the particles.

The Court decided In re Leshin , (125 USPQ 416) the selection of a material of construction based upon its “suitability of intended use, would be entirely obvious”. The claimed latex, ziconia, alumina, titanium, etc. particles are all well known for their inertness, availability and long track record of use with immunological materials. It would have been within the skill of the art to modify Stocker and use any one of the claimed latex, ziconia, alumina, titanium, etc. particles for the above advantages and as selection of a material based upon its suitability of intended use.

Anawls et al. (USP 5,091,318) teach titania, zirconia and alumina are all well known support materials for immunoassay. Additionally, claim 47 claims latex as a support material.

Rohr (USP 5,445,970) also teaches titania, zirconia, latex and alumina are well known support materials for immunoassays.

The Court decided In re Leshin , (125 USPQ 416) the selection of a material of construction based upon its “suitability of intended use, would be entirely obvious”. Anawls et al. and Rohr both teach the claimed latex, ziconia, alumina, titanium, etc. particles are all well known as support materials for immunoassay. It would have been within the skill of the art to modify Stocker in view of either Anawls or Rohr and use any one of the claimed latex, ziconia, alumina, titanium, etc. particles for their well known use in immunoassays as selection of a material based upon its suitability of intended use.

Response to Arguments

The Office has reconsidered Applicant's arguments filed 1/22/07 and has deemed they are not persuasive.

Applicant states in the last paragraph on page 8 that Stocker does not teach use of immobilized receptors that bind target ligands from a sample. These arguments are directed to a method of intended use, which is of no patentable moment with respect to the pending apparatus claims. Stocker teach immobilized receptors that bind specific ligands and has been properly applied here.

Applicant states on page 9 in the third full paragraph the alternative embodiment of the particles having the dimension of between 1 nm and 5 microns is not addressed in the rejections of record. The Office has correctly interpreted the instant claim language as the scenario of a nonporous smooth surface with a receptor immobilized to the surface.

Applicant states on page 9 in the fourth and fifth paragraphs that Stocker does not teach "immobilizing any biological material". Stocker in column 6 lines 22-23 teach immobilizing the sample, which has been properly read on the instant claims.

The remainder of the remarks on page 10 is directed to alternative embodiments. The Office has correctly interpreted the instant claim language as the scenario of a nonporous smooth surface with a receptor immobilized to the surface.

On page 11 Applicant states the antibodies, etc. taught by Stocker are not equivalent to those of the instant invention. These arguments are directed to a method of intended use, which are of no patentable moment with respect to the pending

apparatus claims. Stocker teaches antibodies, etc. and has been properly applied here.

On pages 12-13 Applicant states Stocker does not teach different capture zones that bind different ligands. Stocker teach in column 3 lines 27+ the use of different tissue samples in different wells which has been properly read on the claimed "different target ligands". Additionally, the purpose of Stocker teaching hydrophilic reaction fields surrounded by hydrophobic areas is to isolate different samples from each other further supporting that Stocker teaches analysis of multiple samples simultaneously.

Under items "6-7" on pages 14-15, Applicant stated Stocker does not teach the claimed particle size. As the claims are presently written, the size of 1 nm to 5 microns is not required and is an alternative embodiment. If Applicants were to adapt the suggested amendment for claim 79, the Office would maintain the selection of the claimed size would have been obvious as a result effective variable (In re Boesch 205 USPQ 215).

On page 16 item "8" Applicant states Stocker does not teach "immobilizing any biological material". Stocker in column 6 lines 22-23 teaches immobilizing the sample, which has been properly read on the instant claims.

The remainder of Applicant's remarks state there is no is no motivation to make the 35 USC 103 rejections of record. The Office maintains it would have been within the skill of the art to modify Stocker alone. The Office has also made an alternative 35 USC 103 rejection using Anawls et al. (USP 5,091,318) and Rohr (USP 5,445,970) as secondary references supplying motivation to make the modification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander
Primary Examiner
Art Unit 1743

